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510(k) Summary of Safety and Effectiveness

NOV 2 8 2001

Med-Rx® Extension Sets

Submitter Information:

Bill C.K. Lim
Manager or Regulatory Affairs
Benlan Inc.
2760 Brighton Road
Oakville, Ontario
Canada, L6H 5T4

Phone: (905) 829-5004
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Date 510(k) Summary Prepared: February 23, 2001

Name/Classification of the Device:

Classification Name:	Urological Irrigation System and Tubing Set
Device Name:	Irrigation Set
Proprietary Name:	Med-Rx ® Irrigation Set
Classification Panel:	Class II in CFR 876.5980, Gastro-Urological Irrigation Tray Panel: Gastroenterology

Identification of the Legally Marketed Device to which the Submitter Claims Equivalence:

The Med-Rx ® Irrigation Sets are substantially identical in materials, packaging, sterilization, and intended use to the Baxter series Irrigation sets. 2C4030 and 2C4005, manufactured by Baxter Healthcare Corporation.

Description of the Subject Device:

The Med-Rx® Irrigation Sets consist of a set of PVC tubing which has a urological connector at one end and a spike(s) with a large ratchet pinch clamp at the other end. The set may or may not include a sight chamber and roller clamp.

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Intended Use of the Subject Device:

The Irrigation Sets are to be used in corporation with urological/gastrointestinal devices, such as an endoscope. They are used for the infusion of sterile solutions into the bladder to cleanse (evacuate) the contents of the bladder or other related urological procedures to be carried out by trained medical personnel. Benlan Inc. does not cause or promote new intended uses for these devices. The "Indication for Use Statement" is included on a separate page as Attachment 3 to this submission.

Technological Characteristics of the Subject Device:

The Med-Rx Irrigation Sets have some minor differences from the predicate device. The Med-Rx® TUR tube is made from Non-Latex Material. Med-Rx® Irrigation sets may include either a roller clamp and sight chamber. Med-Rx® TUR Set incorporates a sight chamber and roller clamp. Baxter does not include a sight chamber on either of the predicate devices however in the same category of product (code 2C4041) the sight chamber is included.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2001

Mr. Bill Lim
Manager of Quality
and Regulatory Affairs
Benlan, Inc.
2760 Brighton Road
OAKVILLE, ONTARIO L6H5T4
CANADA

Re: K010607
Trade/Device Name: Med-Rx Irrigation Set
Models 10-3001, 10-3002, 10-3002, 10-4000, 10-4001
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 78 LJH
Dated: October 24, 2001
Received: October 29, 2001

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510(k) Number (if known) K010607

Device Name: Med-Rx® Irrigation Sets

Indications for Use:

The Irrigation Sets are to be used in corporation with urological/gastrointestinal devices, such as an endoscope. They are used for the infusion of sterile solutions into the bladder to cleanse (evacuate) the contents of the bladder or other related urological procedures to be carried out by trained medical personnel. Benlan Inc. does not cause or promote new intended uses for these devices. The "Indication for Use Statement" is included on a separate page as Attachment 3 to this submission.

(Please Do Not Write Below This Line / Continue on Another Page if Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K010607

Prescription Use ✓ OR Over the Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1-2-96)